UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,566	02/15/2002	Brian Brockway	22570-023001	3298

26194 7590 07/25/2008
FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3735	
MAIL DATE	DELIVERY MODE
07/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/077,566	BROCKWAY ET AL.	
	Examiner	Art Unit	
	ROBERT L. NASSER	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,44,48-52,55 and 60-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 10-17, 44, 48-52, 55, and 60-75* is/are rejected.

7)☒ Claim(s) *7-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6, 10, 11, 12, 50, 63, 65-71, 73, and 75 rejected under 35 U.S.C. 103(a) as obvious over Pohndorf et al. With respect to figure 8, Pohndorf teaches a method of implanting a pressure measurement device in the heart of a patient comprising providing a pressure sensor assembly 10 including a pressure transducer located externally of the body (see column 7, line 26) and a pressure transmission tube 530, where the catheter has a distal end, i.e. tube 530, that is more flexible than the proximal catheter portion, 516 and back, and where the proximal portion is more cursh proof than the flexible tube 530. In addition, the tube has radiused corners (atraumatic) so as to provide an atraumatic tip. It is unclear whether the tube 530 is a pressure transmission catheter or not. Given the disclosure of Pohndorf of using PTCs, it is the examiner's position that it would have been obvious to make the tube a catheter with a barrier and a pressure transmission fluid, as it is merely the selection of one known pressure transmitting catheter for another. As such, the catheter has a distal portion having an opening with a barrier, i.e. a membrane (see column 4, lines 26-30). In addition, the pressure transducer is proximal to the distal end portion. The method further includes positioning the catheter across a heart wall, with the distal portion 530 substantially in a heart chamber and the crush resistant portion, including 516, in a

"substantial" portion of the heart wall. The examiner notes that applicant has not defied the term substantial and that it is the examiner's position that any portion of the heart wall penetrated by the catheter is a "substantial" portion. Claim 3 is rejected in that the pressure measurement device is positioned with the catheter across all layers of the heart (see column 7). Claims 4 and 6 are rejected in that the catheter can be positioned across the heart wall, i.e. the ventricular septum, with the opening in the left ventricle (see column 4, lines 57-69). Claim 5 is rejected in that the catheter can also be positioned across the heart into the right ventricle (see column 5, lines 1-11). Claims 10 and 11 are rejected in that the positioning step is done transluminallly, which is surgically. Claims 12 and 69-70 are rejected in that an external pressure sensor is in a housing outside the heart and on the other side of the heart wall from the catheter. With respect to claim 50, the barrier is flush with the end of the catheter. Claims 63 and 65 are rejected in that the barrier is a compliant membrane. Claim 66 is rejected in that Pohndorf states that the pressure sensor may be of the type taught by Anderson 4407296, which is incorporated by reference. Anderson 440726 uses a piezoresistive pressure sensor. Hence, so does Pohndorf. Claims 67 and 68 are rejected for the reasons given above. Claims 71, 73, and 75 are rejected in that Pohndorf uses a separate device from the pressure sensing assembly, i.e. coiled needle 518 which pierces a hole in the heart wall, and has a lumen through which the catheter advances, i.e. the center of the coil. Alternatively, the needle 518 is separate from the pressure sensing structure and had a lumen through which catheter 530 passes.

Claims 2, 13-17, 48, 49, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Eigler et al 6328699. Pohndorf teaches in column 3, lines 19-27 that the pressure transducer is connected to an implanted monitor. Eigler et al further teaches that it is well known in such a system to have the monitor communicate wirelessly to an external device. Hence, it would have been obvious to modify Pohndorf et al to have the implanted monitor communicate wirelessly to an external device, as it is merely the substitution of a known communication method for another. The remaining features of claims 13-17 were discussed above in the anticipation rejection over Pohndorf. In addition, with respect to claims 48 and 49, the device of Pohndorf may be introduced transvenously (see column 5, line 12).

Claims 44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 6409674. With respect to claim 44, in column 8, lines 19-57, Brockway '674 teaches the equivalence of a coiled stabilizer like that of Pohndorf and a mesh stabilizer that promotes tissue in growth. As such, it would have been obvious to modify Pohndorf et al to use a mesh stabilizer, as it is merely the substitution of one known equivalent stabilizer for another. As such, the housing would have a tissue in growth promoting surface, i.e. the one facing the direction of the coiled needle, and an in growth deterring surface, i.e. the remaining portion of the housing. The device would be positioned as claimed in claim 44. With respect to claim 52, Brockway '674 teaches in column 12, line 37 to column 13 line 4, that it is known to provide a dissolvable material on the tip of a pressure transmission catheter, to ease the transluminal delivery of the pressure sensing device. Hence, it would have been

obvious to modify Pohndorf to use a dissolvable material on the tip, to enable easier insertion of the device.

Claims 51 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 4846191. With respect to claim 51, in figure 4, Brockway teaches a barrier recessed from the end of a pressure transmission catheter. Hence, it would have been obvious to modify Pohndorf et al to use such a recessed barrier, as it is merely the substitution of one known functional equivalent catheter for another. Claim 64 is rejected in that the barrier of Brockway is a gel. Hence , it would have been obvious to modify Pohndorf to use a gel for the barrier, as it is merely the substitution of one known barrier for another.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 6409674 and Zheng 6662045. As discussed above, Brockway teaches alternative securing devices, so as barbs or mesh. Hence, it would have been obvious to modify Figure 7 of Pohndorf to use other fixation devices, as it is merely the substitution of one known equivalent device for another. In addition, Zheng teaches delivering a device into the heart wall, where an introducer sheath is initially around the device, and then both the sheath and the device are advanced through the wall. Hence, it would have been obvious to modify the above combination to deliver the device using an introducer sheath, as it is merely the substitution of one known deliver device for another.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf in view of Sommer et al 6132456. Pohndorf teaches that the lead is

introduced via any known way for introducing screw in leads for a pace maker. Sommer teaches such a method, where the lead is disposed at the distal end of an introducer sheath, and advanced to the insertion point, where it is screwed into the heart. Hence, it would have been obvious to modify Pohndorf to use such a delivery technique, as it is merely the use of a conventional delivery technique in the art.

Claims 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eigler et al in view of Pohndorf . Eigler teaches a method of introducing a pressure sensing catheter through a heart wall including providing a sharpened catheter to piece the ehart wall, passing the pressure sensing catheter through the piecing catheter and into the hear chamber, and then removing the piercing catheter, leaving the sensor in place. It does not have the structure of the sensing catheter. However, as discussed above, Pohndorf does have the structure. As such, it would have been obvious to modify Eigler to use the catheter of figure 8 of Pohndorf, as it is merely the substitution of one known sensing catheter for another.

Claims 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 7-9, are rejected in that Pohndorf only has an external sensor in combination with an atraumatic tip. None of the remaining art has the housing with the sensor secured to the heart.

Applicant's arguments filed 4/28/2008 have been fully considered but they are moot in view of the reformulated rejection above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
July 20, 2008